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Final Report of the Maine Drug Return Implementation Group

Maine State Legislature

Maine Office of Policy and Legal Analysis

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STATE OF MAINE
122nd LEGISLATURE
FIRST REGULAR SESSION

Final Report of the MAINE DRUG RETURN IMPLEMENTATION GROUP

March 8, 2005

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Executive Summary

Public Law 2003, Chapter 679 created the Unused Pharmaceutical Disposal Program administered by the Maine Drug Enforcement Agency and established the Maine Drug Return Implementation Group. The implementation group is charged with working on implementation issues for the Unused Pharmaceutical Disposal Program, specifically addressing postal regulations, methods and requirements for packaging for mailing, minimizing drug diversion and theft, public education and encouraging the development of turn-in programs. The public law is included in Appendix A.

History

The implementation group was formed during the fall of 2004, with appointment of 2 members of the House, one member of the Senate, representatives of Maine police chiefs, pharmacies, pharmaceutical manufacturers, an association of medical professionals, the Office of the Attorney General, the Department of Health and Human Services, the Department of Environmental Protection and the Maine Drug Enforcement Agency. The membership of the implementation group is included as Appendix B.

The implementation group held 4 public meetings to review information on environmental and pharmaceutical issues, to receive briefings and to reach consensus on recommendations. The meetings were held in Augusta on October 15, November 12 and December 20, 2004, and January 28, 2005.

Recommendations

- The implementation group recommends the encouragement of local turn-in events for people to drop off unneeded pharmaceuticals for disposal. These programs rely on the voluntary action of individuals, local municipalities, community service organizations and law enforcement agencies for success. The implementation group suggests that the Legislature consider product stewardship, in which the pharmaceutical manufacturers would fund or provide funding for all aspects of local turn-in events.

- The implementation group recommends amendments to the Maine Unused Pharmaceutical Disposal Program, Public Law 2003, Chapter 679, to allow public funding that is not from the General Fund and delay the start date to July 1, 2006. See draft legislation in Appendix E. Once again, product stewardship could be considered to provide funding for the mail-in program.

- The implementation group supports consideration of a drug redistribution program that would accept unneeded, unopened prescription drugs for redistribution to qualified persons who hold prescriptions for those drugs. See Appendix F.

- The implementation group recommends that the Maine Drug Enforcement Agency send a letter to the United States Drug Enforcement Administration supporting amendment to federal regulations to provide a safe and effective method of disposal for controlled substances for individual citizens and law enforcement.

I. INTRODUCTION

Public Law 2003, Chapter 679 created the Unused Pharmaceutical Disposal Program administered by the Maine Drug Enforcement Agency and established the Maine Drug Return Implementation Group. The implementation group is charged with working on implementation issues for the Unused Pharmaceutical Disposal Program, specifically addressing postal regulations, methods and requirements for packaging for mailing, minimizing drug diversion and theft, public education and encouraging the development of turn-in programs. A copy of Public Law 2003, Chapter 679, is attached as Appendix A.

The implementation group was formed during the fall of 2004, with appointment of 2 members of the House, one member of the Senate, and representatives of a local police department, pharmacies, pharmaceutical manufacturers, an association of medical professionals, the Office of the Attorney General, the Department of Health and Human Services, the Department of Environmental Protection and the Maine Drug Enforcement Agency. In addition, the implementation group maintained contact with and invited the participation of representatives of the Office of the United States Attorney for Maine, the United States Drug Enforcement Administration in the United States Department of Justice and the United States Postal Service. A copy of the membership of the implementation group is included as Appendix B.

The implementation group held 4 public meetings to review information on environmental and pharmaceutical issues, receive briefings on state pharmaceutical programs and state and federal law and reach consensus on recommendations. The meetings were held in Augusta on October 15, November 12 and December 20, 2004, and January 28, 2005.

II. BACKGROUND INFORMATION

A. Defining the problem

Unneeded prescription drugs can be a problem. Kept at home, they stack up in the medicine cabinet, age beyond their expiration dates and tempt unsafe use and intentional abuse. Newspaper accounts offer frightening accounts of home invasions with the intent of obtaining prescription narcotics such as OxyContin. Pharmacies are reluctant to take back unneeded drugs or are prohibited by law from doing so. Disposing of unneeded drugs by flushing them down the toilet or discarding them in the trashcan, so that they end up in a landfill, carries risks to the environment. What is a person to do?

B. Environmental issues

Evidence of pharmaceuticals and personal care products (PPCPs) is showing up in tests conducted on various bodies of water around the globe. Scientific testing points to the need for more research, increased public awareness and better stewardship of the world's surface and groundwaters. A leading researcher on PPCPs, Christian Daughton, of the US Environmental Agency, National Exposure Research Laboratory, has called for increased collaboration between

the environmental and medical fields to determine the causes, extent, risks and solutions to the issue of drugs as pollutants. (*Environmental Stewardship and Drugs as Pollutants*, The Lancet, October 5, 2002, by Christian G. Daughton)

Following are some examples of studies on pharmaceuticals and personal care products and their findings:

- Traces of pharmaceuticals and personal care products have been found by the US Geological Survey downstream of wastewater treatment plants and livestock farms in 139 rivers in 30 states. (*Algae Laid Low by Soap and Toothpaste*, Science Update, November 14, 2004 by Hannah Hoag, citing research by Dana Kolpin in 1999 and 2000) Researchers tested for 95 different organic compounds found in pharmaceuticals and household chemicals. At least one of the target organic compounds showed up in 80% of the waterways, with an average of 7 organic compounds per stream and a maximum of 38 organic compounds in one stream.
- Chemicals that find their ways into streams, by way of sewage, and that are not effectively destroyed by sewage treatment plants include antibiotics, antidepressants, anti-cancer drugs, tranquillizers, blood lipid regulators and other well-known drugs such as Viagra. (*Pharmaceuticals and Personal Care Products in the Environment: Agents of Subtle Change?* Environmental Health Perspectives, December 1999 by Christian Daughton and Thomas Ternes)
- One NuvaRing women's controlled release estrogen dispenser contains after use 2.4 milligrams of estrogen, enough to interfere with the reproduction systems of fish. (*Contraceptive Ring Could Pose Risks After Its Disposal*, Science News, January 25, 2004, by Janet Raloff)

The scientific community recognizes that further research is warranted on the environmental impact of pharmaceuticals and personal care products that reach the environment through excretion from the body, washing dermally applied medications or disposal through flushing or landfilling. Some deposition is inevitable as wastewater cannot treat for most pharmaceuticals and personal care products, but improper flushing is avoidable with consumer education and the development of sound disposal options.

C. Federal and state requirements

Hazardous waste

The Federal Resource Conservation and Recovery Act (RCRA) classifies household pharmaceuticals as household hazardous waste and exempts them from federal regulations governing the disposal of hazardous waste. Having adopted the provisions of RCRA, Maine has chosen to regulate household pharmaceuticals as solid waste, making disposal of unneeded drugs by a household member in a landfill or sewer system legal. When prescription drugs are separated from household waste and accumulated from more than one individual, those accumulated drugs are considered hazardous waste under state and federal laws and must be disposed of in compliance with those requirements.

A drug that is a controlled substance, categorized on a federal list as Schedule II through V, is viewed differently from pharmaceuticals that are not controlled substances. Once a controlled substance is in the hands of the prescription holder, a law enforcement agent in the course of conduct of official duties is authorized to accept that drug. The officer must dispose of accumulated controlled substances as hazardous waste through a witnessed burn at a licensed waste incinerator. Federal law prohibits all others, including reverse distributors, from accepting controlled substances from individuals and law enforcement officers, thus increasing the difficulty and cost of law enforcement in effecting disposal.

Some prescription and nonprescription drugs are considered hazardous waste because of their chemical make-up or characteristics. These drugs also must be disposed of as hazardous waste, at a licensed hazardous waste incinerator facility. If they are not controlled substances disposal does not have to be by a witnessed burn.

Mailing and shipping requirements

A program for mailing in unneeded prescription drugs must comply with federal requirements for mailing, following the US Postal Service Domestic Mail Manual and the rules adopted under that manual,. The program must also comply with any requirements from the Controlled Substances Act, the U.S. Environmental Protection Agency and the U.S. Drug Enforcement Administration. As prescription drugs already regularly travel via the mail in this country to consumers, the technology of appropriate packaging exists and is reasonably priced.

Sending accumulated unneeded prescription drugs out of state for disposal as hazardous waste requires the services of a licensed transporter of hazardous waste. The implementation group noted that hiring personnel to identify and separate controlled substances from other drugs could be very expensive but would lower disposal costs for the drugs that are not controlled substances. Not separating the drugs would save on substantial personnel costs and increase disposal costs as all of the drugs would have to be disposed of as if they were controlled substances.

D. Current approaches

Lacking clear direction on methods for disposing of unneeded prescription drugs, Maine residents choose a variety of approaches. They store them up at home, seek the cooperation of their dispensing pharmacy to take them back and dispose of them, flush them into the sewer and send them to the landfill or incinerator plant. The Penobscot County AARP Triad has just begun small scale turn-in events and a larger 1-day event held in South Portland at a pharmacy resulted in the collection of 55,000 pills, enough to fill a 55 gallon container. Public Law 2003, Chapter 679 establishes a mail-in program contingent on acquiring outside funding which is scheduled to begin July 1, 2005 if funding is available.

The implementation group reviewed the volume of drugs being prescribed, the practices of Maine's nursing facilities and hospitals and the requirements of the MaineCare program. Data presented to the group provided a snapshot of the type and amount of drugs being prescribed in the state. The implementation group appreciates the cooperation of the Maine Health Care

Association, the Maine Hospital Association, the MaineCare program within the Department of Health and Human Services, Anthem Blue Cross Blue Shield, the Maine State Employees Health Insurance Program, the University of Maine Systems health plan and the Maine Education Association Benefits Trust.

From the information provided, the implementation group considered the following items to be particularly useful when looking at the big picture of prescription drugs and their disposal:

- Maine's nursing facilities are aware of the problem of unneeded prescription drugs, of the need for safe disposal and the potential benefits of returning unneeded drugs. Controlled substances and medicines that come in bulk and formulations such as ointments and cortisone must be regularly and methodically destroyed. Unit doses that are unopened are returned to the pharmacy for credit and repackaging whenever possible. Handling of medications is done only by trained staff, with paperwork requirements and storage and dispensing procedures that would not be practical in a household setting.
- Maine's hospital pharmacies handle a broad array of prescription drugs. They utilize reverse distributors, which are companies that accept unused drugs, return whatever is possible to the manufacturers and dispose of expired and out of date drugs, drugs the manufacturers would not accept back and drugs on the federal RCRA list. Drugs that are not hazardous waste under Maine DEP rule may be managed as medical waste and incinerated. RCRA hazardous waste drugs are disposed of as hazardous waste and are shipped to disposal sites out of state. Unmedicated intravenous fluids and controlled substances are disposed of into the sewer system.
- The MaineCare program reimburses pharmacies and hospitals for prescription drugs for members enrolled in the MaineCare program. In order to avoid excess dispensing, MaineCare controls the length of time for which drugs may be dispensed, according to the nature of the drug. The program requires nursing and other health care facilities to identify unneeded drugs on a monthly basis, requires that drugs in unit dose packages be returned for credit and requires the destruction of unneeded medications not returned for credit.
- In order to learn the extent of prescription drug use in Maine, the implementation group reviewed the quantities of prescription drugs reimbursed each month by 3 large health coverage programs. The Maine State Employees Health Insurance Program reimburses pharmacies for an average of 136,427 prescriptions each month, of which 2193 are for narcotics. The Maine Education Association Benefits Trust reimburses pharmacies for an average of 205,474 prescriptions per month, of which 2629 are for narcotics. The University of Maine Systems health plan reimburses pharmacies for an average of 40,500 prescriptions per month, of which 533 are for narcotics.

III. RECOMMENDATIONS

A. Voluntary turn-in events

The implementation group reviewed voluntary turn-in events for unneeded prescription drugs and recommends encouraging turn-in events on the local level. The implementation group anticipates an increasing number of these events and greater amounts of collected unneeded drugs. The implementation group recommends that the Legislature consider product stewardship for voluntary turn-in events in order to provide continuing responsibility from pharmaceutical manufacturers for their products, including funding for education, outreach, collection, disposal and reporting.

Coordination

The implementation group recommends that the Maine Department of Environmental Protection, the Maine Drug Enforcement Agency, the Department of Health and Human Services and the Department of the Attorney General work together with manufacturers to enable more turn-in events to be held successfully. Coordination is needed to ensure that turn-in events are safe and convenient for individual citizens who participate, provide safeguards for the collection and identification of turned-in drugs and comply with state and federal law and rule regarding the handling of controlled substances and hazardous waste. The implementation group suggests that a statistically valid sampling of collected unneeded drugs be done and recorded to provide information about drug prescribing and waste.

Educational materials and outreach

The implementation group suggests that the Office of the Attorney General, the Departments of Environmental Protection and Health and Human Service, the Maine Medical Association and the Maine Hospital Association work together to prepare informational materials for interested parties, participating municipalities, law enforcement, medical personnel and community service organizations. Good information on how to successfully hold a voluntary turn-in event will increase the number of events, public participation and success.

Funding

Funding for collection, transportation, storage and disposal would enable a greater number of turn-in events to be held successfully. Funds may be needed for law enforcement, statistical sampling, reporting and disposal. The implementation group suggests that individuals and entities interested in voluntary turn-in events pursue funding for their local events and that the Legislature consider product stewardship to provide funding.

Starting date

A starting date for voluntary turn-in events is not required because of their voluntary nature. If product stewardship were applied to voluntary turn-in events, a start date would be needed for manufacturer responsibility to begin.

B. Mail-in program

Public Law 2003, Chapter 679, which created the Unused Pharmaceutical Disposal Program, recognized that the enabling legislation was incomplete and established the implementation group to provide guidance to the Legislature. Specifically the legislation mentions the need for recommendations regarding postal regulations, methods and requirements for mailing packaging, minimizing drug diversion and theft and public education. The implementation group reached consensus on recommendations to move the disposal program forward. The implementation group recommends that the Legislature consider adding a product stewardship model to the mail-in program.

Packaging for mailing

The implementation group suggests that pharmaceutical manufacturers or the State or both provide the mailing packaging for the mail-in program that meets the requirements of the United States Postal Service and the Maine Drug Enforcement Agency. The implementation group recommends that the mailing packaging be made available at pharmacies, hospitals, physicians' offices and health clinics.

Mail receipt, storage and disposal

The implementation group recommends that the Maine Drug Enforcement Agency determine whether drugs would be mailed directly to MDEA or to a consolidator under contract with MDEA. MDEA rulemaking is necessary to establish the protocols for mailers and mailing, statistical sampling and reporting and disposal of drugs. Transportation to a disposal site, which is required to be done by a licensed handler of hazardous waste, would be accomplished by the consolidator. Hazardous waste disposal sites would accept the shipments of unneeded drugs shipped from Maine and would dispose of them by incineration.

Educational materials and outreach

The implementation group suggests that educational materials for pharmaceutical manufacturers, pharmacies, hospitals, physicians' offices, health clinics, law enforcement and individual citizens be provided by the Office of the Attorney General, the Departments of Environmental Protection and Health and Human Service, the Maine Medical Association, the Maine Hospital Association and the drug manufacturers, all within the limits of their existing resources.

Funding

Public Law 2003, Chapter 679 requires non-public funding in order to begin the mail-in program. Funding will be required for the prepaid mailers, distribution, postage, storage and disposal and public education materials. The implementation group recommends that Public Law 2003, Chapter 679 be amended in 22 MRSA section 2700, subsection 5, to allow receipt of non-General Fund public funding, including federal funds. Suggested legislation is included as Appendix E.

Starting date

The implementation group recommends that the starting date for the Unused Pharmaceutical Disposal Program be changed to allow for additional preparation time for the adoption of rules and the acquisition of funding. The implementation group recommends that Public Law 2003, Chapter 679, section 4 should be amended to provide for an effective date of July 1, 2006. Suggested legislation is included as Appendix E.

C. Product stewardship

Product stewardship is a concept that recognizes the responsibility of the manufacturer of a product from the manufacturing process through final disposal in an environmentally sound manner. The implementation group recommends that the Legislature consider a product stewardship model for voluntary turn-in programs and the mail-in program for prescription drugs, recognizing the cooperative efforts of individual citizens, prescription drug manufacturers and State government to provide safe collection and disposal for those drugs. If product stewardship were to be adopted by the Legislature, the implementation group recommends a starting date of July 1, 2007.

D. General recommendations

- The implementation group recommends that the Maine Legislature consider legislation to establish a redistribution program for unneeded pharmaceuticals. Under this program Maine residents of low and medium income who hold a valid prescription would be eligible to obtain for a very low fee prescription drugs that had been donated to the program from health facilities, drug manufacturers, drug wholesale and terminal distributors and hospitals. The drugs would all be unopened and packaged in tamper-evident unit dose packages or they would be unopened injectable, aerosol or topical medications. The program would not distribute controlled substances, drugs that had been tampered with or drugs within 6 months of their expiration date. See Appendix F for suggested legislation.

- The implementation group recommends that a letter be sent by the Maine Drug Enforcement Agency to the United States Drug Enforcement Administration supporting amendment to federal regulations to provide individual citizens and law enforcement safe and effective methods of disposal for controlled substances.

APPENDIX A

Public Law 2003, Chapter 679
An Act to Encourage the Proper Disposal of Unneeded Pharmaceuticals

APPROVED | CHAPTER
MAY 05 '04 | 679
BY GOVERNOR | PUBLIC LAW

STATE OF MAINE

IN THE YEAR OF OUR LORD TWO THOUSAND AND FOUR

S.P. 671 - L.D. 1826

An Act To Encourage the Proper Disposal of Unused Pharmaceuticals

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA c. 604 is enacted to read:

CHAPTER 604

DISPOSAL OF UNUSED PHARMACEUTICALS

§2700. Unused Pharmaceutical Disposal Program

1. **Establishment; purpose.** There is established the Unused Pharmaceutical Disposal Program, referred to in this chapter as "the program." The purpose of the program is to ensure the safe, effective and proper disposal of unused pharmaceuticals. For purposes of compliance with federal law and regulation, the return of pharmaceuticals under this section is deemed to be for law enforcement purposes.

2. **Administration.** The program is administered by the Maine Drug Enforcement Agency, referred to in this chapter as "the agency," established in Title 25, section 2955.

3. **Return of pharmaceuticals.** The agency shall create a system for the return of unused pharmaceuticals. The system must use prepaid mailing envelopes into which the unused

pharmaceuticals are placed and returned to a single collection location. The prepaid mailing envelopes must be made available to the public at various locations, including, but not limited to, pharmacies, physicians' offices and post offices. The agency may randomly assess the toxicity of materials received under the program as long as the assessment results do not identify the patient, person who mailed the material, prescriber or pharmacy.

4. Disposal of pharmaceuticals. The agency shall ensure that only agency officers handle the unused pharmaceuticals received pursuant to subsection 3. The unused pharmaceuticals must be disposed of by the agency in a manner that is designed to be effective, secure and in compliance with local, state and federal environmental requirements, including the federal Resource Conservation and Recovery Act of 1976, as amended.

5. Unused Pharmaceutical Disposal Program Fund; funding. The Unused Pharmaceutical Disposal Program Fund, referred to in this chapter as "the fund," is established within the agency to be used by the director of the agency to fund or assist in funding the program. Any balance in the fund does not lapse but is carried forward to be expended for the same purposes in succeeding fiscal years. The fund must be deposited with and maintained and administered by the agency. The agency may accept funds into the fund from any non-General Fund, nonpublic fund source, including grants or contributions of money or other things of value, that it determines necessary to carry out the purposes of this chapter. Money received by the agency to establish and maintain the program must be used for the expenses of administering this chapter.

6. Rulemaking. The agency shall adopt rules to carry out the purposes of this chapter. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

Sec. 2. Maine Drug Return Implementation Group. The Maine Drug Return Implementation Group, referred to in this section as "the implementation group," is established to work on implementation issues for the Unused Pharmaceutical Disposal Program, established in the Maine Revised Statutes, Title 22, chapter 604, referred to in this section as "the program."

1. Issues. The implementation group shall study the following issues and make recommendations for implementation of the program in a manner that addresses the issues, safeguards the public health and environment and meets the requirements of local, state and federal law, rule and regulation:

A. Postal regulations;

B. The methods and requirements for packaging, including prepaid mailing envelopes;

C. Minimizing drug diversion and theft;

D. Public education regarding program requirements and operation; and

E. Encouraging the development of drug drop-off programs at the local level.

2. Membership. The implementation group consists of 11 members.

A. The President of the Senate shall appoint one Senator, one representative of local municipal enforcement agencies and one representative of pharmacies. The appointed Senator serves as chair of the implementation group.

B. The Speaker of the House shall appoint 2 representatives, one person representing pharmaceutical manufacturers and one representative of a statewide association of medical professionals.

C. The implementation group must also include the Attorney General or the Attorney General's designee, the Commissioner of Human Services or the commissioner's designee, the Commissioner of Environmental Protection or the commissioner's designee and the Director of the Maine Drug Enforcement Agency or the director's designee.

The implementation group shall invite the participation of the federal Drug Enforcement Agency, the Office of the United States Attorney for the District of Maine, the United States Postal Service and interested parties and persons with expertise and interest in issues related to the disposal of unused pharmaceuticals.

All appointments must be made by September 1, 2004. The appointing authorities shall notify the Executive Director of the Legislative Council upon making their appointments. When appointment of all members of the implementation group is completed, the chair shall call and convene the first meeting no later than September 30, 2004.

3. Staffing. Staffing must be provided by a statewide association of medical professionals and, upon approval of the Legislative Council, the Office of Policy and Legal Analysis.

4. Compensation. Legislative members of the implementation group are entitled to the legislative per diem, as defined in the Maine Revised Statutes, Title 3, section 2, and reimbursement for travel and other necessary expenses related to their attendance at authorized meetings of the group. Public members not otherwise compensated by their employers or other entities that they represent are entitled to receive reimbursement of necessary expenses and, upon a demonstration of financial hardship, a per diem equal to the legislative per diem for their attendance at authorized meetings of the implementation group.

5. Report. The implementation group shall report to the joint standing committee of the Legislature having jurisdiction over health and human services matters by January 31, 2005. The report must include information and recommendations on implementing the program. The joint standing committee of the Legislature having jurisdiction over health and human services matters shall review the report and may report out legislation to the First Regular Session of the 122nd Legislature.

6. Extension. If the implementation group requires a limited extension of time to conclude its study and make its report, it may apply to the Legislative Council, which may grant an extension.

7. Funding. The implementation group shall seek outside funds to fully fund all costs of the implementation group. If sufficient outside funding has not been received by September 15, 2004 to fully fund all costs of the implementation group, no meetings are authorized and no expenses of any kind may be incurred or reimbursed. Contributions to support the work of the implementation group may not be accepted from any party having a pecuniary or other vested interest in the outcome of the matters being studied. Any person, other than a state agency, desiring to make a financial or in-kind contribution must certify to the Legislative Council that it has no pecuniary or other vested interest in the outcome of the study. Such certification must be made in the manner prescribed by the Legislative Council. All contributions are subject to approval by the Legislative Council. All funds accepted must be forwarded to the Executive Director of the Legislative Council along with an accounting record that includes the amount of funds, the date the funds were received, from whom the funds were received and the purpose of and any limitation on the use of those funds. The Executive Director of the Legislative Council shall administer any funds received by the implementation group. The executive director shall notify the chair of the implementation group when sufficient funding has been received.

Sec. 3. Appropriations and allocations. The following appropriations and allocations are made.

LEGISLATURE

Miscellaneous Studies - Funding

Initiative: Allocates funds for the per diem and expenses of members of the Maine Drug Return Implementation Group and printing a report in fiscal year 2004-05.

Other Special Revenue Funds	**2003-04**	**2004-05**
Personal Services	$0	$660
All Other	0	2,200
Other Special Revenue Funds Total	$0	$2,860

Sec. 4. Effective date. That section of this Act that enacts the Maine Revised Statutes, Title 22, chapter 604 takes effect July 1, 2005.

APPENDIX B

Membership list, Maine Drug Return Implementation Group

Maine Drug Return Implementation Group

Public Law 2003, Chapter 679

Friday, March 3, 2005

Appointment(s) by the President

Sen. John L. Martin	Member of the Senate
Mr. Douglas Carr	Representing Pharmacies
Chief James Toman	Representing Local Municipal Enforcement Agencies

Appointment(s) by the Speaker

Rep. William M. Earle	Member of the House
Rep. Susanne P. Ketterer	Member of the House
Katherine Bilotas	Representing Pharmaceutical Manufacturers
Stevan Gressitt, MD	Representing a Statewide Association of Medical Professionals

Director, Maine Drug Enforcement Agency
Roy Mckinney, Director

Designee of Attorney General
James Cameron, Assistant Attorney General

Designee of Commissioner, Department of Environmental Protection
Ann Pistell, Environmental Specialist

Designee of Commissioner, Department of Human Services
Sally-Lou Patterson, Director

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APPENDIX C

Chart of Options for Drug Return Programs

Disposal of Unused Pharmaceuticals
Options Chart, January 28, 2005
* Indicates a product stewardship model

Voluntary Drug Turn-in	
Without product stewardship	**With product stewardship***
	Manufacturers file plan for approval with MDEP, MDEA
MDEA adopt rules	Same
Community sponsor	Same
Law enforcement receives drugs	Same
Statistical sampling of drugs identified and recorded	Same
Law enforcement disposes of drugs as required by state and federal law. May ship to consolidator for later disposal.	Same
Law enforcement reports results to MDEA	Same
Education and outreach by AG, MDEA, MDEP, Me Medical Assoc., Me Hospital Assoc., DHHS within their resources	Same parties provide education and outreach, plus manufacturers
State funding not required Funding from other sources optional	Funding from manufacturers Funding from other sources optional
Start date not needed	Start date 7//1/07
Mail-in program	
Without product stewardship	**With product stewardship***
	Manufacturers file plan for approval with MDEP, MDEA
MDEA adopt rules	Same
MDEA sponsors	MDEA or manufacturers sponsor
Mailers distributed to hospitals, pharmacies, physicians' offices, health centers. Program funds mailers and mailing costs.	Same procedures. Manufacturers pay for mailers and mailing.
Consumer mails to MDEA or to consolidation facility under contract with MDEA for disposal as hazardous waste. Statistical sample identified for recording and reporting. Program funds sampling and disposal costs.	Same procedures. Manufacturers fund sampling and disposal.
MDEA reports results	Manufacturers report results to MDEA
Education and outreach by AG, MDEA, MDEP, Me Medical Assoc., Me Hospital Assoc., DHHS within their resources and as funded by program	Same procedures with participation of manufacturers. Manufacturers fund education and outreach.
Funding needed, private and non-General Fund public funding.	Funding by manufacturers, other sources optional.
Enforcement by AG	Same
Start date 7/1/05	Start date 7/1/07

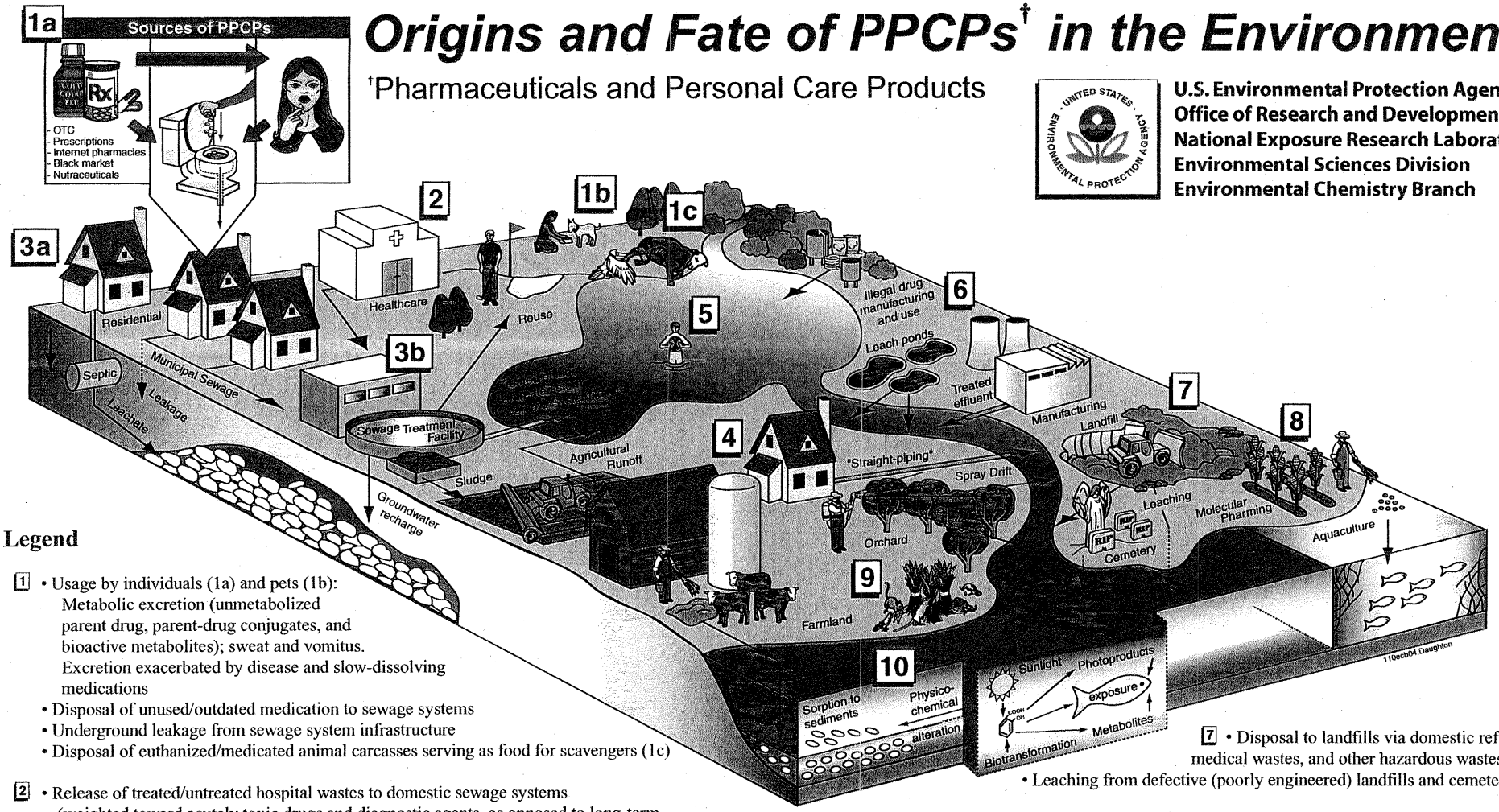
APPENDIX D

Origins and Fate of PPCPs in the Environment
By Christian G. Daughton
http://epa.gov/nerlesd1/chemistry/pharma/images/drawing.pdf

Origins and Fate of PPCPs† in the Environment

†Pharmaceuticals and Personal Care Products

U.S. Environmental Protection Agency
Office of Research and Development
National Exposure Research Laboratory
Environmental Sciences Division
Environmental Chemistry Branch



Legend

1 • Usage by individuals (1a) and pets (1b):
Metabolic excretion (unmetabolized parent drug, parent-drug conjugates, and bioactive metabolites); sweat and vomitus.
Excretion exacerbated by disease and slow-dissolving medications
• Disposal of unused/outdated medication to sewage systems
• Underground leakage from sewage system infrastructure
• Disposal of euthanized/medicated animal carcasses serving as food for scavengers (1c)

2 • Release of treated/untreated hospital wastes to domestic sewage systems (weighted toward acutely toxic drugs and diagnostic agents, as opposed to long-term medications); also disposal by pharmacies, physicians, humanitarian drug surplus

3 • Release to private septic/leach fields
• Treated effluent from domestic sewage treatment plants discharged to surface waters or re-injected into aquifers (recharge)
• Overflow of untreated sewage from storm events and system failures directly to surface waters

4 • Transfer of sewage solids ("biosolids") to land (e.g., soil amendment/fertilization)
• "Straight-piping" from homes (untreated sewage discharged directly to surface waters)
• Release from agriculture: spray drift from tree crops (e.g., antibiotics)
• Dung from medicated domestic animals (e.g., feed) - CAFOs (confined animal feeding operations)

5 • Direct release to open waters via washing/bathing/swimming

6 • Discharge of regulated/controlled industrial manufacturing waste streams
• Disposal/release from clandestine drug labs and illicit drug usage

7 • Disposal to landfills via domestic refuse, medical wastes, and other hazardous wastes
• Leaching from defective (poorly engineered) landfills and cemeteries

8 • Release to open waters from aquaculture (medicated feed and resulting excreta)
• Future potential for release from molecular pharming (production of therapeutics in crops)

9 • Release of drugs that serve double duty as pest control agents:
examples: 4-aminopyridine, experimental multiple sclerosis drug → used as avicide; warfarin, anticoagulant → rat poison; azacholesterol, antilipidemics → avian/rodent reproductive inhibitors; certain antibiotics → used for orchard pathogens; acetaminophen, analgesic → brown tree snake control; caffeine, stimulant → *coqui* frog control

10 Ultimate environmental transport/fate:
• most PPCPs eventually transported from terrestrial domain to aqueous domain
• phototransformation (both direct and indirect reactions via UV light)
• physicochemical alteration, degradation, and ultimate mineralization
• volatilization (mainly certain anesthetics, fragrances)
• some uptake by plants
• respirable particulates containing sorbed drugs (e.g., medicated-feed dusts)

Christian G. Daughton, U.S. EPA-Las Vegas

January 2004
(original February 2001)

http://epa.gov/nerlesd1/chemistry/pharma/images/drawing.pdf
from: http://epa.gov/nerlesd1/chemistry/pharma/

APPENDIX E

An Act Regarding the Unneeded Pharmaceutical Disposal Program

Draft
Legislation extending mail-in program start date 1 year and allowing acceptance of federal and nonfederal grant funding
File: G:\2004 Studies\Drug Return\extend start date.doc
Date: January 28, 2005

Title: An Act Regarding the Unused Pharmaceutical Disposal Program

Sec. 1. 22 MRSA §2700, subsection 5 is amended to read:

5. Unused Pharmaceutical Disposal Program Fund; funding. The Unused Pharmaceutical Disposal Program Fund, referred to in this chapter as "the fund," is established within the agency to be used by the director of the agency to fund or assist in funding the program. Any balance in the fund does not lapse but is carried forward to be expended for the same purposes in succeeding fiscal years. The fund must be deposited with and maintained and administered by the agency. The agency may accept funds into the fund from any non-General Fund~~, nonpublic fund~~ source, including grants or contributions of money or other things of value, that it determines necessary to carry out the purposes of this chapter. Money received by the agency to establish and maintain the program must be used for the expenses of administering this chapter.

Sec. 2. Public Law 2003, Chapter 679, section 4 is amended to read:

Sec. 4. Effective date. That section of this Act that enacts the Maine Revised Statutes, Title 22, chapter 604 takes effect July 1, ~~2005~~ 2006.

SUMMARY

This bill allows the acceptance into the Unused Pharmaceutical Disposal Program fund of public funds that are not General Fund funds and extends the beginning date from July 1, 2005 to July 1, 2006.

APPENDIX F

An Act to Establish the Unneeded Prescription Drug Redistribution Program

Draft Drug Return and Redistribution Program
January 28, 2005
File: G:\2004 Studies\Drug Return\Draft Drug Return and Redistribution Program.doc

Title: An Act to Establish the Unused Prescription Drug Redistribution Program

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA §254-C is enacted to read:

§254-C. Unused prescription drug redistribution program

There is established within the department the unused prescription drug redistribution program, referred to in this section as "the program," to make prescription drugs available to low-income persons.

1. Collaboration. The department shall work collaboratively with hospitals, health clinics and federally qualified, Indian Health Service-sponsored and rural health centers to make prescription drugs available to qualified persons through the program.

2. Qualified persons. An individual is a qualified person if that individual meets the eligibility criteria set forth in this subsection.

A. An individual must have family income below 350% of the federal nonfarm income official poverty level, as defined by the federal Office of Management and Budget and revised annually in accordance with the United States Omnibus Budget Reconciliation Act of 1981, Section 673, Subsection 2.

B. An individual must be a legal resident of the State.

C. An individual must have a valid prescription for the drug to be dispensed through the program.

D. An individual may not receive MaineCare prescription drug benefits.

3. Accepting unused prescription drugs. The program may accept unused prescription drugs from drug manufacturers, drug wholesale or terminal distributors, hospitals, health clinics, federally qualified and rural health centers, nursing facilities and assisted living facilities licensed by the department as provided in this paragraph.

A. The program may accept unused prescription drugs that are unopened and packaged in tamper-evident unit dose packages or that are unopened injectable, aerosol or topical medications.

B. The program may accept unused prescription drugs from an entity donating under this subsection if:

(1) The entity is the owner of the prescription drug; or

(2) The entity has maintained custody of the prescription drug for an individual and donation of the prescription drug is accompanied by signed consent to the donation from the individual or authorized representative of the individual.

C. The program may accept unused prescription drugs that are controlled substances as defined by 21 Code of Federal Regulations, Part 1308 and regulations adopted by the federal Department of Justice, Drug Enforcement Administration as allowed by federal law and regulation.

D. The program may not accept unused prescription drugs that have been opened, tampered with or compromised in any way, that have not been stored as directed by the manufacturer, that are within 6 months of their expiration date or that have been held in the custody of the person to whom the prescription drug was originally dispensed.

4. Dispensing donated prescription drugs. The program shall dispense donated prescription drugs to qualified persons through hospitals, health clinics and federally qualified, Indian Health Service-sponsored and rural health centers, nursing facilities and assisted living facilities that volunteer to participate in the program. The program shall pay to the dispensing entity a dispensing fee equal to the dispensing fee provided under the MaineCare program.

5. Fees. To support the program the department may charge nominal fees as provided in this subsection.

A. The department may charge fees to entities making donations of unused prescription drugs under subsection 3.

B. The department may charge fees to persons to whom prescription drugs are dispensed under the program. A fee charged under this paragraph may not exceed the co-payment charged for a similar prescription drug under the MaineCare program.

6. Immunity. A drug manufacturer, drug wholesale or terminal distributor, hospital, health clinic, federally qualified, Indian Health Service-sponsored or rural health center, nursing facility or assisted living facility that makes a donation under subsection 3 or dispenses drugs under subsection 4 is immune from civil or criminal liability for the act of donating or the consequences of the donation or the act of dispensing.

7. Rulemaking. The department, after collaboration with the Maine Board of Pharmacy and the Maine Drug Enforcement Agency, shall adopt rules to implement the program. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

SUMMARY

This bill establishes the unused prescription drug redistribution program under which unused prescription drugs are accepted and dispensed to low-income persons. To be eligible for the program a person must have family income below 350% of the federal poverty level, must not receive MaineCare prescription drug benefits, must be a Maine resident and must have a valid prescription for the drug to be dispensed. The program may accept unused and unopened prescription drugs from drug manufacturers, drug wholesale and terminal distributors, hospitals, health clinics, federally qualified and rural health centers, nursing facilities and assisted living facilities licensed by the Department of Health and Human Services. The bill provides civil and criminal immunity for an entity making a donation to the program. The bill directs the Department of Health and Human Services to adopt implementing rules, designated as routine technical rules, after consultation with the Maine Board of Pharmacy and the Maine Drug Enforcement Agency.